

## REMARKS

### 1. STATUS OF CLAIMS

Claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-94 were pending.

In the Action of July 30, 2008, the Examiner stated that claims 30, 31, 33-36, 38-40, 42, 44-46, 51, 67-69, 72, and 86-93 were allowable. In the Action of November 14, 2008, the Examiner withdrew the allowability of those claims and rejected them. On February 17, 2009, Applicants amended the claims, offering claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-94 for prosecution, and presented arguments against the rejections. In the most recent Action of June 9, 2009, the Examiner stated that Applicants' arguments supporting the allowability of claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-94 were moot in view of the new grounds of rejection of the claims.

Applicants have amended claims 34 and 93 for self-consistency of grammar in referring to singular instances of the recited elements. No new matter is introduced thereby.

Applicants have canceled claim 94.

Claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-93 currently are pending.

### 2. THE OFFICE ACTION OF JUNE 9, 2009

#### Rejections

The Examiner, in a Non-Final Office Action mailed June 9, 2009, rejected all of the pending claims in the application.

A. Claims 30, 31, 34-36, 44-46, 67-69, 72, 86-89, and 91-93 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kolb et al. U.S. 6,797,856 ("Kolb").

B. Claims 51 and 94 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kolb.

### 3. ARGUMENTS AGAINST EXAMINER'S REJECTIONS

Applicants respectfully traverse the Examiner's rejections of claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-93 and request reconsideration and withdrawal of the rejections based on the above claim amendments and the following remarks.

**A. REJECTION OF CLAIMS 30, 31, 34-36, 44-46, 67-69, 72, 86-89, AND 91-93 UNDER 35 U.S.C. § 102(e) AS BEING ANTICIPATED BY KOLB.**

The Examiner asserts that Kolb discloses a substrate having a coating of polymeric molecules formed by the polymerization of a diallyldialkylammonium salt. The Examiner also asserts that the polymeric molecules are considered to be non-leachably bound to the substrate because they “are intended to remain bound to the substrate during use of the absorbent article” The Examiner asserts other details from Kolb to conclude that Kolb anticipates Applicants’ invention as recited in claims 30, 31, 34-36, 44-46, 67-69, 72, 86-89, and 91-93. Applicants respectfully disagree.

Applicants assert that Kolb does not teach “polymers of dimethyl ammonium chloride” (polyDADMAC) nor polymers of diallyldialkylammonium salt which are non-leachably bound to a substrate. Kolb does disclose binding agents and describes them as being “capable of immobilizing microorganisms such as *E. coli* and other fecal associate bacteria, fungi and protozoans [col 1, ln 37-40]. The passage in Kolb [col. 6, ln 16-27] cited by the Examiner describes suitable cationic compounds which are **binding agents used to trap microorganisms**. The list of cationic compounds includes polymeric and non-polymeric compounds. For example, chitosan and polyacrylamides are polymers. In contrast, quaternary ammonium and octadecyldimethoxysilylpropylammonium chloride are not polymers.

Diallyldimethylammonium chloride (DADMAC) is disclosed in the list of cationic compounds. DADMAC is not a polymer. **DADMAC** can be polymerized to form **polyDADMAC**, which is a polymer. Applicants assert that Kolb is very specific about which compounds are disclosed as being useful to trap microorganisms in the disclosed swimwear. Applicants submit herewith the declarations of Dr. Christopher D. Batich and Dr. James F. Kirk. Each of these declarants has studied the Kolb reference and has concluded that **Kolb’s reference to DADMAC is not a disclosure of the use of polyDADMAC** in a manner pertinent to the presently-claimed subject matter.

Applicants assert that Kolb fails to teach or to suggest “**polymeric molecules formed by the polymerization of a diallyldialkylammonium salt**” as recited in claim 30. Furthermore, Kolb fails to teach or to suggest “**polymeric molecules formed by the polymerization of a diallyldimethylammonium salt or DADMAC**” as recited in claims 31, 67, 91, and 92. Claims 34-36, 44-46, 68-69, 72, 86-89, and 93 depend from the above-cited claims and incorporate their recitation of “polymeric molecules...” such as polyDADMAC. Kolb does not disclose the more general term “diallyldialkylammonium salt” within the specification at all. It has been held that a species anticipates a claim to the genus [*In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989)]. Applicants agree that the disclosure of **DADMAC**

monomer in Kolb anticipates the genus of the monomer, diallyldialkylammonium salt. However, Applicants assert that without a disclosure of **polyDADMAC**, Kolb cannot anticipate the genus consisting of polymers of diallyldialkylammonium salts. In order to anticipate a claim the reference must teach each and every element in the claim (MPEP § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Because Kolb does not disclose each and every limitation recited in claims 30, 31, 34-36, 44-46, 67-69, 72, 86-89, and 91-93, Kolb does not anticipate these claims.

Applicants request that the Examiner withdraw the anticipation rejection and allow claims 30, 31, 34-36, 44-46, 67-69, 72, 86-89, and 91-93.

**B. REJECTION OF CLAIMS 51 and 94 UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER KOLB.**

Applicants have canceled claim 94, therefore the rejection is moot in regards to that claim.

The Examiner asserts that Kolb teaches all other aspects of the invention but is silent regarding the method of bonding of the polymeric molecules to the substrate. The Examiner relies on Kolb's disclosure of binding agents to be fixed on the substrate to support the assertion that it would have been obvious to have "fixed" the polymeric molecules onto the substrate with covalent bonds. Applicants respectfully disagree.

Even though Kolb discloses [col 1, ln 44-50 and col 5, ln 52-56] that binding agents may be permanently attached to a surface or waste dam, Kolb is silent regarding the means of attachment. Kolb does not disclose or suggest that the binding agents be **non-leachably or covalently bonded** to the surface sites of the waste dam. Kolb does not disclose or suggest that **polyDADMAC** be covalently bound to a substrate. Furthermore, Kolb does not even disclose polyDADMAC in any context, nor does Kolb provide any teaching or suggestion for covalently binding polyDADMAC to a substrate. There would be no reason for one of ordinary skill in the art to look to Kolb for guidance on preparing "**polymeric molecules formed by the polymerization of diallyldimethylammonium chloride**" as recited in claim 51, because no such enabling disclosure is provided by Kolb. Applicants assert that Kolb, therefore, does not provide a disclosure to make obvious Applicants' recitation in claim 51 that the "polymeric molecules are non-leachably and covalently bonded to the surface sites of said substrate".

In the alternative, Applicants rely on their priority document U.S. Provisional Application 60/111,472 filed December 8, 1998 which predates Kolb. Applicants point to claims 1, 2, and 3; page 4, lines 5-15; page 5, lines 3-24; and page 5, line 25 to page 6, line 6 of the provisional application as filed to support the

subject matter of claim 51. Those sections describe *inter alia* antimicrobial compositions wherein the “structure is less prone to reacting with acids and bases”. Applicants assert that the latter phrase is equivalent to “non-leachably and covalently bonded to surface sites” recited in claim 51.

Applicants’ provisional application discloses [page 5, line 25 to page 6, line 6] that “the chemical structure produced by the method is less prone to reacting with acids and bases produced by bacterial growth”. Applicants assert that the language of the priority document is support for the recitation of **non-leaching** as defined in the present application at paragraphs [0056 and 0057].

Therefore, Applicants assert that Kolb is not a proper reference for the Examiner to cite regarding the subject matter of claim 51. The subject matter of claims 51 was disclosed within the specification of Applicants’ provisional application which predates Kolb.

Applicants respectfully request the Examiner to withdraw the obviousness rejection of claim 51 and allow the claim.

#### **4. ADDITIONAL ARGUMENTS OF APPLICANTS**

##### **A. FURTHER SUPPORT FOR NON-OBVIOUSNESS**

Under 35 U.S.C. § 103 a “patent may not be obtained ..... if the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art...” One should also consider the inferences and creative steps that person of ordinary skill in the art would employ, *KSR International, Inc. v. Teleflex, Inc.* 550 U.S. 398, 411, 82 USPQ2d 1385, 1397 (2007). In addition, secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, and industry recognition, may serve as evidence of non-obviousness, *Graham v. John Deere Col.* 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Applicants assert that one of ordinary skill in the art would not have conceived of Applicant’s invention as claimed. In support of the assertion, Applicants note that the FDA reviewer, who would be expected to be highly skilled in the art, rejected the opportunity to find that one embodiment of Applicants invention did not provide a predictable benefit. The FDA reviewer determined that there was no substantially similar predicate device from which to make a pre-market approval determination. Instead a *de novo* review process was required. Applicants assert that the FDA reviewer’s determination supports that the embodiment was not an obvious variation of prior art devices.

For further support for the non-obviousness of Applicants’ invention, we point the Examiner to the following statements concerning the process that Quick-Med

Technologies, Inc.<sup>1</sup> followed to obtain FDA registration for the use of polyDADMAC on textiles as a sterile barrier wound dressing intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

Generally an applicant seeking FDA approval of a device submits a 510(k) pre-market notification to demonstrate that the new device is “substantially equivalent” to a previous cleared 510(k) device, a predicate device. However, if a device is not found to be substantially equivalent to a predicate device, then the device is automatically placed in Class III. High risk devices so classified must undergo premarket approval (PMA) under section 515 in order to be reclassified in to class I or II. However, a low-risk device in class III may be reclassified into class I or II under a modified PMA under Section 513(f)(2) of 21 U.S.C. § 360c(f), also known as “*de novo*” or “risk-based” classification. The *de novo* pathway to PMA is therefore used for low-risk devices for which there is no predicate device with which it can be compared to establish suitability for commercial distribution. Once the device has been reclassified in class I or II, it may serve as a predicate device for future substantially similar devices. Section 513(f)(2) of 21 U.S.C. § 360c(f) is submitted herewith for review.

During an August 28, 2006 meeting of agents of Quick-Med Technology and FDA personnel, the FDA determined that use of polyDADMAC on textiles for wound dressings had no suitable predicate and was a new technology eligible for pre-market approval under section 513(f)(2), the *de novo* pathway. Therefore, the FDA would not grant pre-market approval for this use of polyDADMAC via the standard 510(k) process because there was no comparable device that could serve as a suitable predicate for the device. After a lengthy *de novo* review process, FDA granted approval of polyDADMAC on February 25, 2009. The new class 21 CFR 878.4015 was developed for polyDADMAC. The description is given below.

“A wound dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC)<sup>2</sup> additive is a device that is a sterile barrier wound dressing intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. The device consists of a textile substrate and permanently bound pDADMAC. The device acts as a physical barrier to outside contaminants and does not act on the surface or interior of the wound nor does it contain antimicrobial agents that act on the body.”

Applicants assert that the class III designation and subsequent section 513(f)(2) (*de novo*) premarket approval process support that polyDADMAC on textiles is non-obvious over prior art devices. The FDA determined that the device, polyDADMAC on textiles for wound dressings, was a class III as a device. That

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<sup>1</sup> Quick-Med Technologies, Inc. is one of the assignees of the present patent application.

<sup>2</sup> The FDA documents use the term “pDADMAC” to refer to poly(diallyldimethylammonium chloride), which is the same compound Applicants’ specification refers to as polyDADMAC.

means that there was no predicate device which was substantially similar to it. A *de novo* PMA process was used to determine if the device was suitable for commercial distribution based upon data generated specifically for the device, polyDADMAC on textiles. If there were obvious prior art devices for comparison, then the FDA would not have placed polyDADMAC on textiles in class III. If there was an obvious predicate device then the FDA would have compared polyDADMAC on textiles with such a substantially similar predicate device using the standard 510(k) process. After successfully obtaining FDA approval, polyDADMAC will now serve as a predicate device for future FDA pre-market approval applications. A press release further describing FDA approval of polyDADMAC for use in a wound dressing is submitted herewith.

## **B. APPLICANTS REMARKS REGARDING COMPACT PROSECUTION**

Applicants note that the Kolb reference was cited by the Examiner in prior office actions and was overcome by Applicants. Applicants respectfully submit that the outstanding rejection in this matter seems to contravene the venerable principle of compact prosecution, set out in MPEP §707.07, et seq., and especially the proscription against piecemeal examination in §707.07(g). This principle has recently been reaffirmed in an email to the examining corps by the new Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office, reading in essence:

One key is to expeditiously identify and resolve issues of patentability—that is getting efficiently to the issues that matter to patentability in each case, and working with applicants to find the patentable subject matter and get it clearly expressed in claims that can be allowed. The examiner and the applicant share the responsibility for the success of this process.

On the subject of quality, there has been speculation in the IP community that examiners are being encouraged to reject applications because a lower allowance rate equals higher quality. Let's be clear: patent quality does not equal rejection. In some cases this requires us to reject all the claims when no patentable subject matter has been presented. It is our duty to be candid with the applicant and protect the interests of the public. In other cases this means granting broad claims when they present allowable subject matter. In all cases it means engaging with the applicant to get to the real issues efficiently—what we all know as compact prosecution.

When a claimed invention meets all patentability requirements, the application should be allowed expeditiously. ... [B]y engaging with applicants early on, we certainly can get to the point more quickly, and efficiently allow those claims that are entitled to patent protection.

[Source: <http://www.patentlyo.com/patent/2009/08/director-kappos-patent-quality-equals-granting-those-claims-the-applicant-is-entitled-to-under-our-laws.html>]

See also the official text of Undersecretary Kappos' speech on September 14, 2009, to the Intellectual Property Owners organization (IPO), where he similarly alludes to "incentivizing compact prosecution."  
[[http://www.uspto.gov/main/homepagenews/2009sep14\\_kappos\\_ipo\\_speech.htm](http://www.uspto.gov/main/homepagenews/2009sep14_kappos_ipo_speech.htm)]

## 5. SUMMARY

Applicants respectfully submit that the prior art cited by the Examiner does not anticipate nor make obvious Applicants invention as recited in claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-93. Applicants have provided arguments to support their belief in the allowability of the claims. Applicants assert that the Examiner has misinterpreted the language of the Kolb reference. Applicants have provided the Examiner with the declarations of experts in the art who affirm that the Examiner's interpretation is incorrect. Applicants have provided evidence of secondary consideration, namely documents related to the FDA approval process to lend support that the claimed invention is not obvious over the prior art. Applicants respectfully request the Examiner to withdraw all rejections of the claims and allow claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-93.

Respectfully submitted:

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/s.m.p.m./

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